

**Experiment Number:** 96013-04  
**Test Type:** 90-DAY  
**Route:** Gavage  
**Species/Strain:** Rat/LONG-EVANS

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
**Test Compound:** Melatonin  
**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014  
**Time Report Requested:** 08:54:45  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**C Number:** C96013  
**Lock Date:** 02/28/2003  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date** NONE

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Date Report Requested: 10/21/2014

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First Dose M/F: NA / NA

Lab: BAT

<b>LONG-EVANS Rat Male</b> <b>0 UG/KG</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0
	ANIMAL ID	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1
		1	1	1	1	1	1	1	1	2
		1	2	3	4	5	6	7	8	9
										*TOTALS

**Alimentary System**

Esophagus	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic					1	1	1	1	1	5 1.0
Pancreas	+	+	+	+	+	+	+	+	+	10
Acinus, Atrophy						1				1 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	10
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	10
Stomach, Glandular	+	+	+	+	+	+	+	+	+	10
Tooth					+	+	+	+	+	6
Pulp, Malformation					1	1	1	1	1	6 1.0

**Cardiovascular System**

Blood Vessel	+	+	+	+	+	+	+	+	+	10
Heart	+	+	+	+	+	+	+	+	+	10
Myocardium, Infiltration Cellular, Mononuclear CI	1	1	1		1	1				5 1.0

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

LONG-EVANS Rat Male 0 UG/KG	DAY ON TEST	0 0 0 0 0 0 0 0 0 0									
		0 0 0 0 0 0 0 0 0 0									
		9 9 9 9 9 9 9 9 9 9									
		4 4 4 4 4 4 4 4 4 4									
		0 0 0 0 0 0 0 0 0 0									
ANIMAL ID		0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1
		1	1	1	1	1	1	1	1	1	2
		1	2	3	4	5	6	7	8	9	0

\*TOTALS

Endocrine System

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	+	+	M	+	+	+	+	+	M	8
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10

General Body System

NONE

Genital System

Epididymis	+	+	+	+	+	+	+	+	+	+	10
Preputial Gland	+	+	+	+	+	+	+	+	+	+	10
Cyst				X							1
Prostate	+	+	+	+	+	+	+	+	+	+	10
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	10
Testes	+	+	+	+	+	+	+	+	+	+	10

Hematopoietic System

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10

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Lab: BAT

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	ANIMAL ID	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
<b>*TOTALS</b>										
Spleen	+	+	+	+	+	+	+	+	+	10
Thymus	+	+	+	+	+	+	+	+	+	10
<b>Integumentary System</b>										
Mammary Gland	+	+	+	+	+	+	+	+	+	10
Skin	+	+	+	+	+	+	+	+	+	10
<b>Musculoskeletal System</b>										
Bone	+	+	+	+	+	+	+	+	+	10
<b>Nervous System</b>										
Brain	+	+	+	+	+	+	+	+	+	10
Cranial Nerve, Degeneration					3			2		2.5
Cranial Nerve, Gliosis						1	1	1		3 1.0
<b>Respiratory System</b>										
Lung	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic		1				1	1			3 1.0
Inflammation, Granulomatous							1			1 1.0
Metaplasia, Osseous						1			1	2 1.0
Nose	+	+	+	+	+	+	+	+	+	10
Trachea	+	+	+	+	+	+	+	+	+	10
<b>Special Senses System</b>										
Eye	+	+	+	+	+	+	+	+	+	10

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**First Dose M/F:** NA / NA

**Lab:** BAT

<b>LONG-EVANS Rat Male</b> <b>0 UG/KG</b>	<b>DAY ON TEST</b>	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0
		9	9	9	9	9	9	9	9	9
		4	4	4	4	4	4	4	4	4
	<b>ANIMAL ID</b>	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1
		1	1	1	1	1	1	1	1	2
		1	2	3	4	5	6	7	8	9
										0

**\*TOTALS**

Harderian Gland

+ + + + + + + + + + 10

**Urinary System**

Kidney

+ + + + + + + + + + 10

Mineralization

2 1 1 1 1 1 1 1 1 5 1.2

Nephropathy

1 1 1 1 1 1 1 1 1 3 1.0

Urinary Bladder

+ + + + + + + + + + 10

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**Time Report Requested:** 08:54:46

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Male</b><br><b>5 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|--|--------------------|---|---|---|---|---|---|---|---|----------------|
|  |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|  |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9              |
|  |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4              |
|  | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|  |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|  |                    | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2              |
|  |                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2              |
|  |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9              |
|  |                    |   |   |   |   |   |   |   |   | <b>*TOTALS</b> |

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

 +   +   +   +   +   +   +   +   +   +   10

**General Body System**

NONE

**Genital System**

NONE

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

NONE

**Nervous System**

NONE

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First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>5 UG/KG | DAY ON TEST | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
|--------------------------------|-------------|---------------------|---|---|---|---|---|---|---|---|---|
|                                |             | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
|                                |             | 9 9 9 9 9 9 9 9 9 9 |   |   |   |   |   |   |   |   |   |
|                                |             | 4 4 4 4 4 4 4 4 4 4 |   |   |   |   |   |   |   |   |   |
|                                |             | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
| ANIMAL ID                      |             | 0                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                |             | 0                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                |             | 2                   | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                |             | 1                   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
|                                |             | 1                   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

Respiratory System

NONE

Special Senses System

|                                 |   |   |   |   |   |   |   |   |   |   |       |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Eye                             | + | + | + | + | + | + | + | + | + | + | 10    |
| Harderian Gland                 | + | + | + | + | + | + | + | + | + | + | 10    |
| Infiltration Cellular, Lymphoid |   |   |   |   |   | 2 |   |   |   |   | 1 2.0 |
| Inflammation, Chronic           | 1 |   |   |   | 2 |   |   |   |   |   | 2 1.5 |
| Pigmentation                    | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2.0   |

Urinary System

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

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**Time Report Requested:** 08:54:46

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Male</b><br><b>50 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|---|--------------------|---|---|---|---|---|---|---|---|----------------|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9              |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4              |
|   | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3              |
|   |                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2              |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9              |
|   |                    |   |   |   |   |   |   |   |   | <b>*TOTALS</b> |

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

+ + + + + + + + + + 10

**General Body System**

NONE

**Genital System**

Epididymis

+ 1

Atrophy

4 1 4.0

Testes

+ + 2

Bilateral, Germinal Epith, Degeneration

4 1 4.0

Germinal Epith, Degeneration

4 1 4.0

**Hematopoietic System**

NONE

**Integumentary System**

NONE

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Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>50 UG/KG | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---------------------------------|-------------|---|---|---|---|---|---|---|---|---|
|                                 |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                 |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|                                 |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|                                 | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                 |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                 |             | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                 |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
|                                 |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|                                 |             |   |   |   |   |   |   |   |   | 0 |

\*TOTALS

**Musculoskeletal System**

Skeletal Muscle

+ 1

**Nervous System**

NONE

**Respiratory System**

NONE

**Special Senses System**

Eye

++ + + + + + + + + 10

Harderian Gland

++ + + + + + + + + 10

Pigmentation

2 2 2 2 2 5 2.0

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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**Lab:** BAT

| <b>LONG-EVANS Rat Male</b><br><b>5000 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|--------------------|---|---|---|---|---|---|---|---|---|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| ANIMAL ID                                       |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|   |                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

\*TOTALS

**Alimentary System**

|                    |   |       |
|--------------------|---|-------|
| Stomach, Glandular | + | 1     |
| Hyperplasia, Focal | 2 | 1 2.0 |

**Cardiovascular System**

NONE

**Endocrine System**

|               |   |   |   |   |   |   |   |   |   |   |    |
|---------------|---|---|---|---|---|---|---|---|---|---|----|
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | 10 |
|---------------|---|---|---|---|---|---|---|---|---|---|----|

**General Body System**

NONE

**Genital System**

NONE

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

NONE

**Nervous System**

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+ ..Tissue examined microscopically

M ..Missing tissue

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**Lab:** BAT

| <b>LONG-EVANS Rat Male</b><br><b>5000 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|---|--------------------|---|---|---|---|---|---|---|---|----------------|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9              |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4              |
|   | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4              |
|   |                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2              |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9              |
|   |                    |   |   |   |   |   |   |   |   | <b>*TOTALS</b> |

NONE

**Respiratory System**

NONE

**Special Senses System**

|                       |   |   |   |   |   |   |   |   |   |   |     |
|-----------------------|---|---|---|---|---|---|---|---|---|---|-----|
| Eye                   | + | + | + | + | + | + | + | + | + | + | 10  |
| Harderian Gland       | + | + | + | + | M | + | + | M | + | + | 8   |
| Inflammation, Chronic |   |   |   |   |   | 1 |   | 1 |   | 2 | 1.0 |
| Pigmentation          | 2 | 2 |   | 2 | 2 |   |   | 2 |   | 5 | 2.0 |

**Urinary System**

NONE

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+ ..Tissue examined microscopically

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**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Male</b><br><b>50,000 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|--------------------|---|---|---|---|---|---|---|---|---|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|   | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
|   |                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|   |                    |   |   |   |   |   |   |   |   | 0 |

\*TOTALS

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

+ + + + + + + + + + 10

**General Body System**

NONE

**Genital System**

NONE

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

NONE

**Nervous System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>50,000 UG/KG | DAY ON TEST | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
|-------------------------------------|-------------|---------------------|--|--|--|--|--|--|--|--|--|
|                                     |             | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
|                                     |             | 9 9 9 9 9 9 9 9 9 9 |  |  |  |  |  |  |  |  |  |
|                                     |             | 4 4 4 4 4 4 4 4 4 4 |  |  |  |  |  |  |  |  |  |
|                                     |             | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                           |             | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
|                                     |             | 5 5 5 5 5 5 5 5 5 5 |  |  |  |  |  |  |  |  |  |
|                                     |             | 1 1 1 1 1 1 1 1 1 2 |  |  |  |  |  |  |  |  |  |
|                                     |             | 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |
|                                     |             | *TOTALS             |  |  |  |  |  |  |  |  |  |

Respiratory System

NONE

Special Senses System

|                 |   |   |   |   |   |   |   |   |   |   |     |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----|
| Eye             | + | + | + | + | + | + | + | + | + | + | 10  |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | 10  |
| Pigmentation    |   | 2 |   |   | 2 |   | 2 | 2 |   | 4 | 2.0 |

Urinary System

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

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Experiment Number: 96013-04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>200,000 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |
|--------------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|
|                                      |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|                                      |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|                                      |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
|                                      |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
|                                      |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

## Alimentary System

|                                  |   |   |   |   |   |   |   |   |   |   |       |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus                        | + | + | + | + | + | + | + | + | + | + | 10    |
| Intestine Large, Cecum           | + | + | + | + | + | + | + | + | + | + | 10    |
| Intestine Large, Colon           | + | + | + | + | + | + | + | + | + | + | 10    |
| Intestine Large, Rectum          | + | + | + | + | + | + | + | + | + | + | 10    |
| Intestine Small, Duodenum        | + | + | + | + | + | + | + | + | + | + | 10    |
| Intestine Small, Ileum           | + | + | + | + | + | + | + | + | + | + | 10    |
| Intestine Small, Jejunum         | + | + | + | + | + | + | + | + | + | + | 10    |
| Liver                            | + | + | + | + | + | + | + | + | + | + | 10    |
| Inflammation, Chronic            |   |   |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 6 1.0 |
| Vacuolization Cytoplasmic, Focal |   |   |   |   |   | 1 |   |   |   |   | 1 1.0 |
| Pancreas                         | + | + | + | + | + | + | + | + | + | + | 10    |
| Acinus, Atrophy                  |   |   |   |   |   |   |   | 1 |   | 1 | 1.0   |
| Salivary Glands                  | + | + | + | + | + | + | + | + | + | + | 10    |
| Stomach, Forestomach             | + | + | + | + | + | + | + | + | + | + | 10    |
| Stomach, Glandular               | + | + | + | + | + | + | + | + | + | + | 10    |
| Tooth                            | + |   | + |   |   |   | + |   |   |   | 3     |
| Pulp, Malformation               | 1 | 1 |   |   |   | 1 |   |   | 3 |   | 1.0   |

## Cardiovascular System

|                |   |   |   |   |   |   |   |   |   |   |     |
|----------------|---|---|---|---|---|---|---|---|---|---|-----|
| Blood Vessel   | + | + | + | + | + | + | + | + | + | + | 10  |
| Heart          | + | + | + | + | + | + | + | + | + | + | 10  |
| Cardiomyopathy |   |   |   |   | 1 |   |   | 1 | 2 |   | 1.0 |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

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2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>200,000 UG/KG | DAY ON TEST | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
|--------------------------------------|-------------|---------------------|--|--|--|--|--|--|--|--|--|
|                                      |             | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
|                                      |             | 9 9 9 9 9 9 9 9 9 9 |  |  |  |  |  |  |  |  |  |
|                                      |             | 4 4 4 4 4 4 4 4 4 4 |  |  |  |  |  |  |  |  |  |
|                                      |             | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                            |             | 0 0 0 0 0 0 0 0 0 0 |  |  |  |  |  |  |  |  |  |
|                                      |             | 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |
|                                      |             | 1 1 1 1 1 1 1 1 1 2 |  |  |  |  |  |  |  |  |  |
|                                      |             | 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |
|                                      |             | *TOTALS             |  |  |  |  |  |  |  |  |  |

Myocardium, Infiltration Cellular,  
Mononuclear CI

1 1 1.0

**Endocrine System**

|                    |   |   |   |   |   |   |   |   |   |   |    |
|--------------------|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex     | + | + | + | + | + | + | + | + | + | + | 10 |
| Adrenal Medulla    | + | + | + | + | + | + | + | + | + | + | 10 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | 10 |
| Parathyroid Gland  | + | + | + | + | + | + | + | + | + | + | 10 |
| Pituitary Gland    | + | + | + | + | + | + | + | + | + | + | 10 |
| Thyroid Gland      | + | + | + | + | + | + | + | + | + | + | 10 |

**General Body System**

NONE

**Genital System**

|                              |   |   |   |   |   |   |   |   |     |     |       |
|------------------------------|---|---|---|---|---|---|---|---|-----|-----|-------|
| Epididymis                   | + | + | + | + | + | + | + | + | +   | +   | 10    |
| Preputial Gland              | + | + | + | + | + | + | + | + | +   | +   | 10    |
| Inflammation, Granulomatous  |   |   |   |   |   |   | 1 |   |     |     | 1 1.0 |
| Prostate                     | + | + | + | + | + | + | + | + | +   | +   | 10    |
| Inflammation, Chronic Active |   | 2 |   |   |   |   |   |   | 1   | 2.0 |       |
| Seminal Vesicle              | + | + | + | + | + | + | + | + | +   | +   | 10    |
| Testes                       | + | + | + | + | + | + | + | + | +   | +   | 10    |
| Germinal Epith, Degeneration |   | 1 |   |   |   |   |   | 1 | 1.0 |     |       |

**Hematopoietic System**

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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1-4 ..Lesion qualified as:

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2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>200,000 UG/KG | DAY ON TEST | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
|--------------------------------------|-------------|---------------------|---|---|---|---|---|---|---|---|---|
|                                      |             | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
|                                      |             | 9 9 9 9 9 9 9 9 9 9 |   |   |   |   |   |   |   |   |   |
|                                      |             | 4 4 4 4 4 4 4 4 4 4 |   |   |   |   |   |   |   |   |   |
|                                      |             | ANIMAL ID           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 0                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 0                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                      |             | 6                   | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
|                                      |             | 1                   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
|                                      |             | 1                   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

|                                       |   |   |   |   |   |   |   |   |   |   |   |       |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|-------|
| Bone Marrow                           | + | + | + | + | + | + | + | + | + | + | + | 10    |
| Lymph Node                            |   |   |   |   |   |   |   |   |   |   |   | 1     |
| Inguinal, Inflammation, Granulomatous |   |   |   |   |   |   |   |   |   |   |   | 1     |
| Lymph Node, Mandibular                | + | + | + | + | + | + | + | + | + | + | + | 10    |
| Congestion                            |   |   |   |   |   |   |   |   |   |   |   | 2 2.0 |
| Hyperplasia, Lymphoid                 |   |   |   |   |   |   |   |   |   |   |   | 2 2.0 |
| Lymph Node, Mesenteric                | + | + | + | + | + | + | + | + | + | + | + | 10    |
| Spleen                                | + | + | + | + | + | + | + | + | + | + | + | 10    |
| Thymus                                | + | + | + | + | + | + | + | + | + | + | + | 10    |
| <b>Integumentary System</b>           |   |   |   |   |   |   |   |   |   |   |   |       |
| Mammary Gland                         | + | + | + | + | + | + | M | + | + | + | + | 9     |
| Skin                                  | + | + | + | + | + | + | + | + | + | + | + | 10    |
| <b>Musculoskeletal System</b>         |   |   |   |   |   |   |   |   |   |   |   |       |
| Bone                                  | + | + | + | + | + | + | + | + | + | + | + | 10    |
| <b>Nervous System</b>                 |   |   |   |   |   |   |   |   |   |   |   |       |
| Brain                                 | + | + | + | + | + | + | + | + | + | + | + | 10    |
| Cranial Nerve, Gliosis                |   |   |   |   |   |   | 1 |   |   |   |   | 1 1.0 |
| <b>Respiratory System</b>             |   |   |   |   |   |   |   |   |   |   |   |       |
| Lung                                  | + | + | + | + | + | + | + | + | + | + | + | 10    |
| Foreign Body                          |   |   |   |   |   |   |   |   |   |   | X | 1     |
| Inflammation, Chronic                 |   |   |   |   |   |   | 1 |   |   |   | 1 | 2 1.0 |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

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Route: Gavage

Species/Strain: Rat/LONG-EVANS

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Male<br>200,000 UG/KG | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
|--------------------------------------|-------------|---|---|---|---|---|---|---|---|-------|
|                                      |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
|                                      |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9     |
|                                      |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4     |
|                                      | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
| Metaplasia, Osseous                  |             | 1 |   |   |   |   |   |   | 1 | 1.0   |
| Nose                                 |             | + | + | + | + | + | + | + | + | 10    |
| Inflammation, Chronic                |             |   |   | 1 | 1 | 1 |   |   |   | 3 1.0 |
| Trachea                              |             | + | + | + | + | + | + | + | + | 10    |
| <b>Special Senses System</b>         |             |   |   |   |   |   |   |   |   |       |
| Eye                                  |             | + | + | + | + | + | + | + | + | 10    |
| Harderian Gland                      |             | + | + | + | + | + | + | + | + | 10    |
| Pigmentation                         |             |   |   | 2 | 2 | 2 | 2 | 2 | 2 | 6 2.0 |
| <b>Urinary System</b>                |             |   |   |   |   |   |   |   |   |       |
| Kidney                               |             | + | + | + | + | + | + | + | + | 10    |
| Mineralization                       |             |   | 1 |   |   | 1 | 1 | 1 | 1 | 5 1.0 |
| Nephropathy                          |             |   | 1 | 1 |   |   | 1 | 1 | 1 | 5 1.0 |
| Urinary Bladder                      |             | + | + | + | + | + | + | + | + | 10    |

\*TOTALS

\*\*\*END OF MALE DATA\*\*\*

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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M ..Missing tissue

X ..Lesion present

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Experiment Number: 96013-04

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Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:46

First Dose M/F: NA / NA

Lab: BAT

|                              | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
|------------------------------|-------------|---|---|---|---|---|---|---|---|---------|
|                              | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
| <b>LONG-EVANS Rat Female</b> |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9       |
| <b>0 UG/KG</b>               |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4       |
|                              |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
|                              |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
|                              |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1       |
|                              |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7       |
|                              |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9       |
|                              |             |   |   |   |   |   |   |   |   | *TOTALS |

**Alimentary System**

|                           |   |   |   |   |   |   |   |   |   |     |
|---------------------------|---|---|---|---|---|---|---|---|---|-----|
| Esophagus                 | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Large, Cecum    | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Large, Colon    | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Small, Ileum    | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | 10  |
| Liver                     | + | + | + | + | + | + | + | + | + | 10  |
| Clear Cell Focus          |   | X |   |   |   |   |   |   |   | 1   |
| Inflammation, Chronic     |   | 1 | 1 | 1 | 1 | 1 |   |   | 5 | 1.0 |
| Pancreas                  | + | + | + | + | + | + | + | + | + | 10  |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | 10  |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | 10  |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | 10  |
| Tooth                     |   |   | + | + |   |   | + | + |   | 4   |
| Pulp, Malformation        |   | 1 | 1 |   | 1 | 1 |   | 4 |   | 1.0 |

**Cardiovascular System**

|              |   |   |   |   |   |   |   |   |   |    |
|--------------|---|---|---|---|---|---|---|---|---|----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | 10 |
| Heart        | + | + | + | + | + | + | + | + | + | 10 |

**Endocrine System**

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Route: Gavage

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:47

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>0 UG/KG | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
|----------------------------------|-------------|---|---|---|---|---|---|---|---|---------|
|                                  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
|                                  |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9       |
|                                  |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4       |
|                                  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
| ANIMAL ID                        |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0       |
|                                  |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1       |
|                                  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7       |
|                                  |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9       |
|                                  |             |   |   |   |   |   |   |   |   | *TOTALS |

|                    |   |   |   |   |   |   |   |   |   |   |    |
|--------------------|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex     | + | + | + | + | + | + | + | + | + | + | 10 |
| Adrenal Medulla    | + | + | + | + | + | + | + | + | + | + | 10 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | 10 |
| Parathyroid Gland  | + | + | + | + | + | + | + | + | + | + | 10 |
| Pituitary Gland    | + | + | + | + | + | + | + | + | + | + | 10 |
| Thyroid Gland      | + | + | + | + | + | + | + | + | + | + | 10 |

**General Body System**

NONE

**Genital System**

|                |   |   |   |   |   |   |   |   |   |   |     |
|----------------|---|---|---|---|---|---|---|---|---|---|-----|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | 10  |
| Ovary          | + | + | + | + | + | + | + | + | + | + | 10  |
| Cyst           | X |   | X |   |   |   |   |   |   |   | 2   |
| Uterus         | + | + | + | + | + | + | + | + | + | + | 10  |
| Dilatation     |   |   |   | 2 |   | 2 |   |   | 2 |   | 2.0 |

**Hematopoietic System**

|                        |   |   |   |   |   |   |   |   |   |   |    |
|------------------------|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow            | + | + | + | + | + | + | + | + | + | + | 10 |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | 10 |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | 10 |
| Thymus                 | + | + | + | + | + | + | + | + | + | + | 10 |

**Integumentary System**

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

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1-4 ..Lesion qualified as:

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Experiment Number: 96013-04

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Test Compound: Melatonin

CAS Number: 73-31-4

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Time Report Requested: 08:54:47

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>0 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |
|----------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|
|                                  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                  |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|                                  |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|                                  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                  |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|                                  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|                                  |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

## Integumentary System

|               |   |   |   |   |   |   |   |   |   |   |    |
|---------------|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | 10 |
| Skin          | + | + | + | + | + | + | + | + | + | + | 10 |

## Musculoskeletal System

|      |   |   |   |   |   |   |   |   |   |   |    |
|------|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | 10 |
|------|---|---|---|---|---|---|---|---|---|---|----|

## Nervous System

|                             |   |   |   |   |   |   |   |   |   |   |     |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|-----|
| Brain                       | + | + | + | + | + | + | + | + | + | + | 10  |
| Cranial Nerve, Degeneration |   |   |   |   |   | 2 | 2 |   |   | 2 | 2.0 |
| Pineal Gland, Inflammation  |   |   |   |   |   | 1 |   |   |   | 1 | 1.0 |

## Respiratory System

|                             |   |   |   |   |   |   |   |   |   |   |     |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|-----|
| Lung                        | + | + | + | + | + | + | + | + | + | + | 10  |
| Alveolar Epith, Hyperplasia |   |   |   |   |   | 1 |   |   |   | 1 | 1.0 |
| Inflammation, Chronic       |   |   | 1 |   |   |   | 1 | 1 |   | 3 | 1.0 |
| Metaplasia, Osseous         |   |   |   |   | 1 |   | 1 |   |   | 2 | 1.0 |
| Nose                        | + | + | + | + | + | + | + | + | + | + | 10  |
| Trachea                     | + | + | + | + | + | + | + | + | + | + | 10  |

## Special Senses System

|                 |   |   |   |   |   |   |   |   |   |   |     |
|-----------------|---|---|---|---|---|---|---|---|---|---|-----|
| Eye             | + | + | + | + | + | + | + | + | + | + | 10  |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | 10  |
| Pigmentation    |   | 2 |   |   |   | 2 | 2 |   |   | 3 | 2.0 |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

**Experiment Number:** 96013-04

**Test Type:** 90-DAY

**Route:** Gavage

**Species/Strain:** Rat/LONG-EVANS

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Melatonin

**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>0 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|--------------------|---|---|---|---|---|---|---|---|---|
|  |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|  | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|  |                    | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|  |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|  |                    |   |   |   |   |   |   |   |   | 0 |

\*TOTALS

**Urinary System**

|                 |   |   |   |   |   |   |   |   |   |   |       |
|-----------------|---|---|---|---|---|---|---|---|---|---|-------|
| Kidney          | + | + | + | + | + | + | + | + | + | + | 10    |
| Mineralization  | 1 |   |   | 1 |   | 1 | 1 |   | 1 | 1 | 6 1.0 |
| Nephropathy     | 1 |   |   |   | 1 | 1 |   | 1 | 2 |   | 5 1.2 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | 10    |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
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**Species/Strain:** Rat/LONG-EVANS

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Melatonin

**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>5 UG/KG</b> | <b>DAY ON TEST</b> | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|--------------------|----------------|---|---|---|---|---|---|---|---|
|  |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 9              | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |                    | 4              | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|  | <b>ANIMAL ID</b>   | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 2              | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|  |                    | 6              | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|  |                    | 1              | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|  |                    | <b>*TOTALS</b> |   |   |   |   |   |   |   |   |

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

+ + + + + + + + + + 10

**General Body System**

NONE

**Genital System**

Ovary

+ + + + + + + + + + 10

Angiectasis

3 1 3.0

Cyst

X X X X 4

Uterus

+ + + + + + + + + + 10

Dilatation

1 2 2 2 2 5 1.8

Metaplasia, Squamous

1 1 1.0

**Hematopoietic System**

Lymph Node, Mandibular

+ 1

Hyperplasia, Lymphoid

1 1 1.0

**Integumentary System**

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

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**Experiment Number:** 96013-04

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**Route:** Gavage

**Species/Strain:** Rat/LONG-EVANS

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Melatonin

**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>5 UG/KG</b> | <b>DAY ON TEST</b> | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|--------------------|----------------|---|---|---|---|---|---|---|---|
|  |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 9              | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |                    | 4              | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|  | <b>ANIMAL ID</b>   | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |                    | 2              | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|  |                    | 6              | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|  |                    | 1              | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|  |                    | <b>*TOTALS</b> |   |   |   |   |   |   |   |   |

NONE

**Musculoskeletal System**

NONE

**Nervous System**

NONE

**Respiratory System**

NONE

**Special Senses System**

|                   |   |   |   |   |   |   |   |   |   |   |     |     |
|-------------------|---|---|---|---|---|---|---|---|---|---|-----|-----|
| Eye               | + | + | + | + | + | + | + | + | + | + | 10  |     |
| Retina, Dysplasia |   |   |   |   |   |   |   |   |   |   | 1   | 1.0 |
| Harderian Gland   | + | + | + | + | + | + | + | + | + | + | 10  |     |
| Pigmentation      | 2 |   |   |   |   |   | 2 | 2 | 2 | 4 | 2.0 |     |

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

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**Experiment Number:** 96013-04

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**Route:** Gavage

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**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Melatonin

**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>50 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|--------------------|---|---|---|---|---|---|---|---|---|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 0 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|   |                    | 7 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| ANIMAL ID                                       |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|   |                    | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

\*TOTALS

**Alimentary System**

|                           |   |   |
|---------------------------|---|---|
| Esophagus                 | M | 0 |
| Intestine Large, Cecum    | + | 1 |
| Intestine Large, Colon    | + | 1 |
| Intestine Large, Rectum   | + | 1 |
| Intestine Small, Duodenum | + | 1 |
| Intestine Small, Ileum    | + | 1 |
| Intestine Small, Jejunum  | + | 1 |
| Liver                     | M | 0 |
| Pancreas                  | M | 0 |
| Salivary Glands           | M | 0 |
| Stomach, Forestomach      | M | 0 |
| Stomach, Glandular        | M | 0 |

**Cardiovascular System**

|              |   |   |
|--------------|---|---|
| Blood Vessel | M | 0 |
| Heart        | M | 0 |

**Endocrine System**

|                    |   |   |
|--------------------|---|---|
| Adrenal Cortex     | M | 0 |
| Adrenal Medulla    | M | 0 |
| Islets, Pancreatic | M | 0 |
| Parathyroid Gland  | M | 0 |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:47

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>50 UG/KG | DAY ON TEST | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
|-----------------------------------|-------------|---------------------|---|---|---|---|---|---|---|---|---|
|                                   |             | 0 0 0 0 0 0 0 0 0 0 |   |   |   |   |   |   |   |   |   |
|                                   |             | 0 9 9 9 9 9 9 9 9 9 |   |   |   |   |   |   |   |   |   |
|                                   |             | 7                   | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| ANIMAL ID                         |             | 0                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                   |             | 0                   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                   |             | 3                   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                   |             | 6                   | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |   |
|                                   |             | 1                   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

|                 |                       |   |
|-----------------|-----------------------|---|
| Pituitary Gland | M                     | 0 |
| Thyroid Gland   | M + + + + + + + + + + | 9 |

**General Body System**

NONE

**Genital System**

|                |                     |       |
|----------------|---------------------|-------|
| Clitoral Gland | +                   | 1     |
| Ovary          | + + + + + + + + + + | 10    |
| Angiectasis    | 3                   | 1 3.0 |
| Cyst           | X X X X             | 4     |
| Uterus         | + + + + + + + + + + | 10    |
| Dilatation     | 1 1 1               | 3 1.3 |
| Vagina         | +                   | 1     |
| Cyst           | X                   | 1     |

**Hematopoietic System**

|                                  |   |       |
|----------------------------------|---|-------|
| Bone Marrow                      | + | 1     |
| Myeloid Cell, Hyperplasia        | 4 | 1 4.0 |
| Lymph Node                       | + | 1     |
| Lumbar, Hyperplasia, Plasma Cell | 3 | 1 3.0 |
| Lymph Node, Mandibular           | M | 0     |
| Lymph Node, Mesenteric           | + | 1     |
| Spleen                           | M | 0     |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate  
2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

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Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:47

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>50 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |       |
|-----------------------------------|-------------|---|---|---|---|---|---|---|---|---|-------|
|                                   |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
|                                   |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
|                                   |             | 0 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9     |
| ANIMAL ID                         | 7           | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4     |
|                                   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
|                                   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |
|                                   | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3     |
| *TOTALS                           |             |   |   |   |   |   |   |   |   |   |       |
| Thymus                            | M           |   |   |   |   |   |   |   |   |   | 0     |
| <b>Integumentary System</b>       |             |   |   |   |   |   |   |   |   |   |       |
| Mammary Gland                     | +           |   |   |   |   |   |   |   |   |   | 1     |
| Skin                              | +           |   |   |   |   |   |   |   |   |   | 1     |
| <b>Musculoskeletal System</b>     |             |   |   |   |   |   |   |   |   |   |       |
| Bone                              | +           |   |   |   |   |   |   |   |   |   | 1     |
| <b>Nervous System</b>             |             |   |   |   |   |   |   |   |   |   |       |
| Brain                             | M           |   |   |   |   |   |   |   |   |   | 0     |
| <b>Respiratory System</b>         |             |   |   |   |   |   |   |   |   |   |       |
| Lung                              | M           |   |   |   |   |   |   |   |   |   | 0     |
| Nose                              | +           |   |   |   |   |   |   |   |   |   | 1     |
| Trachea                           | M           |   |   |   |   |   |   |   |   |   | 0     |
| <b>Special Senses System</b>      |             |   |   |   |   |   |   |   |   |   |       |
| Eye                               | M           | + | + | + | + | + | + | + | + | + | 9     |
| Harderian Gland                   | M           | + | + | + | + | + | + | + | + | + | 9     |
| Pigmentation                      |             |   |   |   | 2 |   |   |   |   |   | 1 2.0 |
| <b>Urinary System</b>             |             |   |   |   |   |   |   |   |   |   |       |
| Kidney                            | M           |   |   |   |   |   |   |   |   |   | 0     |
| Urinary Bladder                   | +           |   |   |   |   |   |   |   |   |   | 1     |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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BLANK ..Not examined microscopically

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2) Mild 4) Marked

**Experiment Number:** 96013-04

**Test Type:** 90-DAY

**Route:** Gavage

**Species/Strain:** Rat/LONG-EVANS

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Melatonin

**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>5000 UG/KG</b> | <b>DAY ON TEST</b> | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
|---|--------------------|----------------|---|---|---|---|---|---|---|---|--|
|   |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
|   |                    | 9              | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |  |
|   |                    | 4              | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |  |
| <b>ANIMAL ID</b>                                  |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
|   |                    | 0              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |
|   |                    | 4              | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |  |
|   |                    | 6              | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |  |
|   |                    | 1              | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |  |
|   |                    | <b>*TOTALS</b> |   |   |   |   |   |   |   |   |  |

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

+ + + + + + + + + + 10

**General Body System**

NONE

**Genital System**

Ovary

+ + + + + + + + + + 10

Cyst

X X X X 4

Uterus

+ + + + + + + + + + 10

Dilatation

2 1 2 2 1 5 1.6

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

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**First Dose M/F:** NA / NA

**Lab:** BAT

| LONG-EVANS Rat Female<br>5000 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|
|                                     |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                     |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                     |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| ANIMAL ID                           | 4           | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|                                     | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                     | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                     | 4           | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|                                     | 6           | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|                                     | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |

\*TOTALS

NONE

**Nervous System**

NONE

**Respiratory System**

NONE

**Special Senses System**

|                               |   |   |   |   |   |   |   |   |   |   |     |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|-----|
| Eye                           | + | + | + | + | + | + | + | + | + | + | 10  |
| Cornea, Inflammation, Chronic |   |   |   |   | 2 |   |   |   |   | 1 | 2.0 |
| Iris, Synechia                |   |   |   |   | 3 |   |   |   |   | 1 | 3.0 |
| Harderian Gland               | + | + | + | + | + | + | + | + | + | + | 10  |
| Pigmentation                  |   |   |   | 2 | 2 | 2 |   | 2 |   | 4 | 2.0 |

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

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**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>50,000 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|---|--------------------|---|---|---|---|---|---|---|---|----------------|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9              |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4              |
|   | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0              |
|   |                    | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5              |
|   |                    | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7              |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9              |
|   |                    |   |   |   |   |   |   |   |   | <b>*TOTALS</b> |

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

  + + + + + + + + + +   10

**General Body System**

NONE

**Genital System**

Ovary

  + + + + + + + + + +   10

Cyst

  X X                   X X X X    6

Uterus

  + + + + + + + + + +   10

Dilatation

  2 1 2 1              2 2 1 1    8 1.5

Metaplasia, Squamous

                          1           1 1.0

**Hematopoietic System**

NONE

**Integumentary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal   3) Moderate
- 2) Mild       4) Marked

**Experiment Number:** 96013-04

**Test Type:** 90-DAY

**Route:** Gavage

**Species/Strain:** Rat/LONG-EVANS

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Melatonin

**CAS Number:** 73-31-4

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:54:47

**First Dose M/F:** NA / NA

**Lab:** BAT

| <b>LONG-EVANS Rat Female</b><br><b>50,000 UG/KG</b> | <b>DAY ON TEST</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|--------------------|---|---|---|---|---|---|---|---|---|
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|   |                    | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|   | <b>ANIMAL ID</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|   |                    | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
|   |                    | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|   |                    | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|   |                    |   |   |   |   |   |   |   |   | 0 |

\*TOTALS

**Musculoskeletal System**

NONE

**Nervous System**

NONE

**Respiratory System**

NONE

**Special Senses System**

Eye

  +   +   +   +   +   +   +   +   +   +   10

Harderian Gland

  +   +   +   +   +   +   +   +   +   +   10

Pigmentation

  2      2      2    2    2    2    2    2    2    8    2.0

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:47

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>200,000 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |
|--|-------------|---|---|---|---|---|---|---|---|---|---|
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 |
|  |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

## Alimentary System

|                           |   |   |   |   |   |   |   |   |   |   |     |
|---------------------------|---|---|---|---|---|---|---|---|---|---|-----|
| Esophagus                 | + | + | + | + | + | + | + | + | + | + | 10  |
| Inflammation, Chronic     |   |   |   |   |   |   |   |   |   |   | 2   |
| Intestine Large, Cecum    | + | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Large, Colon    | + | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Small, Ileum    | + | + | + | + | + | + | + | + | + | + | 10  |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | + | 10  |
| Liver                     | + | + | + | + | + | + | + | + | + | + | 10  |
| Inflammation, Chronic     |   |   |   |   |   |   |   |   |   |   | 1   |
| Pancreas                  | + | + | + | + | + | + | + | + | + | + | 10  |
| Acinus, Atrophy           |   |   |   |   |   |   |   |   |   |   | 1   |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | + | 10  |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | + | 10  |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | + | 10  |
| Tooth                     |   |   |   |   |   |   |   |   |   |   | 4   |
| Pulp, Malformation        | 1 | 1 | 1 | 1 |   |   |   |   |   |   | 4   |
|                           |   |   |   |   |   |   |   |   |   |   | 1.0 |

## Cardiovascular System

|              |   |   |   |   |   |   |   |   |   |   |    |
|--------------|---|---|---|---|---|---|---|---|---|---|----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | 10 |
| Heart        | + | + | + | + | + | + | + | + | + | + | 10 |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:47

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>200,000 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |
|--|-------------|---|---|---|---|---|---|---|---|---|---|
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
|  |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
|  | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 |
|  |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

\*TOTALS

## Endocrine System

|                    |   |   |   |   |   |   |   |   |   |   |    |
|--------------------|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex     | + | + | + | + | + | + | + | + | + | + | 10 |
| Adrenal Medulla    | + | + | + | + | + | + | + | + | + | + | 10 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | 10 |
| Parathyroid Gland  | + | + | + | + | + | + | + | + | + | + | 10 |
| Pituitary Gland    | + | + | + | + | + | + | + | + | + | + | 10 |
| Thyroid Gland      | + | + | + | + | + | + | + | + | + | + | 10 |

## General Body System

NONE

## Genital System

|                |   |   |   |   |   |   |   |   |   |   |       |
|----------------|---|---|---|---|---|---|---|---|---|---|-------|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | 10    |
| Ovary          | + | + | + | + | + | + | + | + | + | + | 10    |
| Cyst           | X | X | X |   |   |   | X |   |   |   | 4     |
| Mineralization |   |   |   |   |   |   | 1 |   |   |   | 1 1.0 |
| Uterus         | + | + | + | + | + | + | + | + | + | + | 10    |
| Dilatation     | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 1 |   | 8 1.8 |

## Hematopoietic System

|                        |   |   |   |   |   |   |   |   |   |   |    |
|------------------------|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow            | + | + | + | + | + | + | + | + | + | + | 10 |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | 10 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | 10 |
| Spleen                 | + | + | + | + | + | + | + | + | + | + | 10 |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal    3) Moderate  
 2) Mild        4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

## P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:48

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>200,000 UG/KG | DAY ON TEST |   |   |   |   |   |   |   |   |     |     |
|--|-------------|---|---|---|---|---|---|---|---|-----|-----|
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0   | 0   |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0   | 0   |
|  |             | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9   | 9   |
|  |             | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4   | 4   |
|  | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0   | 0   |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0   | 0   |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6   | 6   |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6   | 6   |
|  |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9   | 0   |
| *TOTALS                                |             |   |   |   |   |   |   |   |   |     |     |
| Spleen                                 |             | + | + | + | + | + | + | + | + | +   | 10  |
| Thymus                                 |             | + | + | + | + | + | + | + | + | +   | 10  |
| <b>Integumentary System</b>            |             |   |   |   |   |   |   |   |   |     |     |
| Mammary Gland                          |             | + | + | + | + | + | + | + | + | +   | 10  |
| Skin                                   |             | + | + | + | + | + | + | + | + | +   | 10  |
| <b>Musculoskeletal System</b>          |             |   |   |   |   |   |   |   |   |     |     |
| Bone                                   |             | + | + | + | + | + | + | + | + | +   | 10  |
| <b>Nervous System</b>                  |             |   |   |   |   |   |   |   |   |     |     |
| Brain                                  |             | + | + | + | + | + | + | + | + | +   | 10  |
| Cranial Nerve, Degeneration            |             |   |   |   |   |   |   | 1 |   | 1   | 1.0 |
| <b>Respiratory System</b>              |             |   |   |   |   |   |   |   |   |     |     |
| Lung                                   |             | + | + | + | + | + | + | + | + | +   | 10  |
| Metaplasia, Osseous                    |             |   |   |   |   |   |   | 1 |   | 1   | 1.0 |
| Nose                                   |             | + | + | + | + | + | + | + | + | +   | 10  |
| Trachea                                |             | + | + | + | + | + | + | + | + | +   | 10  |
| <b>Special Senses System</b>           |             |   |   |   |   |   |   |   |   |     |     |
| Eye                                    |             | + | + | + | + | + | + | + | + | +   | 10  |
| Harderian Gland                        |             | + | + | + | + | + | + | + | + | +   | 10  |
| Pigmentation                           |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2.0 |     |

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

A ..Autolysis precludes evaluation

I ..Insufficient tissue

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

- 1) Minimal 3) Moderate
- 2) Mild 4) Marked

Experiment Number: 96013-04

Test Type: 90-DAY

Route: Gavage

Species/Strain: Rat/LONG-EVANS

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Melatonin

CAS Number: 73-31-4

Date Report Requested: 10/21/2014

Time Report Requested: 08:54:48

First Dose M/F: NA / NA

Lab: BAT

| LONG-EVANS Rat Female<br>200,000 UG/KG | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|-------------|---|---|---|---|---|---|---|---|---|
|  | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
|  |             | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 |
|  |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

\*TOTALS

Urinary System

|                           |   |   |   |   |   |   |   |   |   |   |       |
|---------------------------|---|---|---|---|---|---|---|---|---|---|-------|
| Kidney                    | + | + | + | + | + | + | + | + | + | + | 10    |
| Mineralization            | 1 | 1 |   | 1 |   | 1 |   | 1 | 1 |   | 6 1.0 |
| Nephropathy               |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   | 8 1.0 |
| Renal Tubule, Hyperplasia |   |   | 1 |   |   |   |   |   |   |   | 1 1.0 |
| Urinary Bladder           | + | + | + | + | + | + | + | + | + | + | 10    |

\*\* END OF REPORT \*\*

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

M ..Missing tissue

X ..Lesion present

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1-4 ..Lesion qualified as:

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- 2) Mild 4) Marked